

### **REMARKS**

The present communication responds to the final Office action of January 18, 2007 in which the Examiner rejected claims 30-81. Claims 30-43, 48-59, and 64-77 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 5,383,865 ("Michel"). Claims 44-47, 60-63 and 78-81 were rejected under 35 U.S.C. § 103(a) as unpatentable over Michel in view of U.S. Patent 6,200,296 ("Dibiasi et al.").

Claims 30-42, 48-55, 57-59, and 64-72, 74-76 and 82-89 are pending in the application. Claims 43-47, 56, 60-63, 73 and 77-81 have been cancelled. Claims 30, 32-36, 38, 40, 41, 48-51, 54, 58, 59, 64, 66-70, 72, 74 and 75 have been amended. New claims 82-89 have been added. No new subject matter has been added to the claims.

The claim rejections are traversed in view of the amendments and for at least the reasons articulated below.

Reconsideration is requested.

#### **Rejection under 35 U.S.C. § 102**

Claims 30-43, 48-59 and 64-77 were rejected under 35 U.S.C. §102(b) as anticipated by Michel.

Claims 43, 56, 73 and 77 have been cancelled obviating the rejection thereof.

Michel discloses "a medication dispensing device 20 in the form of a pen. Pen 20 comprises an injector device 22 and a cartridge assembly 24 that is threaded onto injector 22." (Michel, col. 4, lines 28-31). Michel also discloses:

A metal rod 72 is provided within injector 22 and is axially movable therein. Rod 72 is threaded throughout the length thereof, as indicated at 74. Rod 72 also includes flats 76 on the surface thereof. Rod 72 is housed within a driving sleeve 78 comprising an internally threaded distal end 80 which engages threads 74 of rod 72, an enlarged diameter portion 73 including ribs 75 formed thereon, a reduced diameter portion 77 having ribs 79 formed thereon, and an externally threaded proximal end 82. . . . Driving sleeve 78 cooperates with an outer sleeve

81. The combination of sleeves may collectively be referred to as a dosage sleeve.

(*Id.* at col. 5, lines 14-32). A clutch mechanism is disclosed:

a clutch mechanism 150 is provided for preventing movement of knob 88 in a counterclockwise locking direction. Clutch 150 comprises a movable piece 152 and an axially movable locking seat 168 disposed within stationary piece 154. Movable piece 152 is generally cylindrical in shape and includes a distal end having a plurality of inclined teeth 156 formed about the circumference thereof, as shown in FIG. 7. Each tooth 156 includes a corresponding groove 158 adjacent a stop surface 160. The opposite (proximal) end of movable piece 152 includes a circumferential groove 162 therein, which defines a lip 164, as shown in FIGS. 3 and 4. A spring 165 is disposed in movable piece 152 to bias piece 152 in a proximal direction. As best shown in FIG. 16, movable piece 152 includes a plurality of circumferentially spaced internal grooves which receive ribs 75 of enlarged diameter portion 73 of sleeve 78. Thus, movable piece 152 is movable with sleeve 78 both axially and rotatably.

(*Id.* at col. 6, lines 37-55).

Michel does not disclose that at least one first rotational stopper is secured against rotating by the dosage setting member and at least one second rotational stopper is secured against rotating by the casing as recited in amended claims 30, 48, and 58. Nor does Michel disclose at least one first rotational stopper is secured against rotating by the dosage setting member and the at least one second rotational stopper is secured against rotating by the drive device as recited in amended claims 34, 50 and 64. To the contrary, Michel discloses a clutch mechanism 150 including a movable piece 152 *movable* with sleeve 78 both axially and *rotatably*.

Michel also does not disclose that at least one first rotational stopper is formed as a unitary piece with the dosage setting member and at least one second rotational stopper is formed as a unitary piece with the at least one translational stopper as recited in amended claims 41 and 75. Instead Michel discloses the clutch mechanism 150 discussed above and shown in FIGS. 3 and 4.

For at least the preceding reasons, a rejection of claims 30, 34, 41, 48, 50, 58, 64 and 75 under 35 U.S.C. §102(b) is unwarranted.

Rejection of the Dependent Claims

Because claims 31-33, 35-40, 42, 49, 51-55, 57, 59, 65-72, 74 and 76 depend directly or indirectly from the independent claims and incorporate all the limitations of the corresponding independent claims, they are allowable for the same reasons and, further, in view of their additional recitations.

Rejection under 35 U.S.C. § 103

Claims 44-47, 60-63 and 78-81 were rejected under 35 U.S.C. § 103(a) as unpatentable over Michel in view of Dibiasi et al.

Claims 44-47, 60-63 and 78-81 have been cancelled obviating thereof.

New Claims

New claims 82-89 have been added, without adding new matter. Support can be found in general throughout the specification and, in particular in FIGS 21 and 22, and page 29, line 16 to page 30, line 5.

Conclusion

This paper does not generate any fees. However, the Commissioner is hereby authorized to charge any deficiencies and credit any overpayments associated with this paper to Deposit Account No. 04-1420.

The application now stands in allowable form, and entry, reconsideration and allowance are requested.

Respectfully submitted,

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